

## REMARKS

Responsive to the Office Action mailed October 13, 2006 and with an extension of time of THREE MONTHS, the present paper is timely filed on or before April 13, 2006. By the present Amendment, claim 24 is amended and no claims are added.

Entry of the amendments and reconsideration of the Application are respectfully requested.

### The Claim Amendments

Claim 24 is amended to point out with even greater particularity that the novel powder that is the product of Applicants' inventive process must have a Hausner ratio  $\leq 1.3$ . Support for the amendment can be found, for example, in the specification at, for example, page 4, line 11 and in the claims as filed.

Applicants respectfully submit that the present amendments do not add new matter to the Application.

### Claim Rejections Under 35 U.S.C. § 102

Claim 24 was rejected under 35 U.S.C. § 102(b) as allegedly anticipated by United States Patent 5,859,258 (Breen et al.). Because Breen et al. does not teach all of the limitations of Applicants' claims, Applicants respectfully traverse.

The Office maintains a mistaken claim construction that ignores the limitation to Hausner ratio  $\leq 1.3$ . At page 5, the Examiner appears to ignore his own construction and *acknowledges* that the difference between the claimed material and the material of the prior art is the Hausner ratio.). Applicants respectfully submit that the Office cannot adopt internally inconsistent claim constructions in arguing different rejections. On the basis of this acknowledged difference between the instant invention and the prior art, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Moreover, Applicants respectfully submit that the Office cannot automatically ignore the plain limitation in the preamble to claim 24. *See, e.g., Diversitech Corp. v. Century Steps*, 850 F.2d 675 (Fed. Cir. 1980). In any event, Applicants respectfully submit that the present amendments to claim 24 render the rejection moot and, for his additional reason, that the rejection should therefore be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claim 24 was rejected as allegedly anticipated by Breen et al. in view of Cheronis, Semimicro Experimental Organic Chemistry, Chapter 5 (1958) (hereafter Cheronis) or in view of Harry G. Brittain, Polymorphism in Pharmaceutical Solids, 334 – 338 (1999) (hereafter Brittain). Because Breen et al., alone or in combination with either or both of Cheronis and Brittain, neither teaches nor suggests all of the limitations of Applicants' claims, Applicants respectfully traverse.

Applicants point out at paragraph [008] of that losartan potassium of the prior art suffers from poor powder flow characteristics. The mechanical advantage (Hausner ratio their specification  $\leq 1.3$  and attendant improved flowability) are the direct effect of subjecting losartan potassium to Applicants' inventive process that includes the step of (re)slurrying, not recrystallizing, losartan potassium in one of a limited number of solvents. Applicants have surprisingly discovered that Hausner ratio  $\leq 1.3$  and attendant improved flowability result from subjecting losartan potassium to this and the other steps recited in claim 24.

A composition of matter may be claimed in terms of the process of making that composition, without regards to knowledge of exactly what the process does on a microscopic or molecular scale. See, e.g., M.P.E.P. § 706.03. Applicants need not know what structural or physical characteristics result from this treatment result in the aforesaid mechanical advantages. Applicants respectfully submit that *In re Conn and Norman*, 119 U.S.P.Q. 388 (Pat. & Tr. Office Bd. App. 1956), does not require otherwise.

Breen et al. discloses solid losartan potassium. Breen et al., does not teach or suggest the steps of Applicants' inventive process that yields their novel losartan potassium having Hausner ratio  $\leq 1.3$ . Cheronis teaches recrystallization of organic compounds. Cheronis does not teach or suggest a slurry step as part of process that does not include recrystallization. The Office has not pointed to anything in Breen et al. that would have suggested to the skilled artisan of the day that recrystallization taught by Cheronis could be modified to a slurry step with a reasonable expectation that losartan potassium having Hausner ratio  $\leq 1.3$  would result.

To support a *prima facie* obviousness rejection, the cited references, alone or in combination with each other or knowledge in the art at the time the invention was made, must, *inter alia* teach or suggest all the claim elements (limitations). See M.P.E.P. § 2143.

Brittain discloses that milling can be used as the final step in a production process of a bulk drug substance. Brittain does not teach or suggest that steps prior to milling have any effect on Hausner ratio. Applicants respectfully submit that even *if* the skilled artisan *were* motivated to mill the solid losartan potassium disclosed by Breen et al., neither Breen et al. nor Brittain, alone or in combination, teach all of the steps (elements) of the process that yield Applicants novel losartan potassium powder having Hausner ratio  $\leq 1.3$ . Accordingly, Applicants respectfully submit that the rejection should be withdrawn.

### Conclusion

Applicants respectfully submit that, based on the foregoing amendments and remarks. The claims are now in condition for allowance, which allowance is earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would advance prosecution of the Application, the Examiner is invited to call the undersigned attorney.

**REQUEST FOR EXTENSION OF TIME**

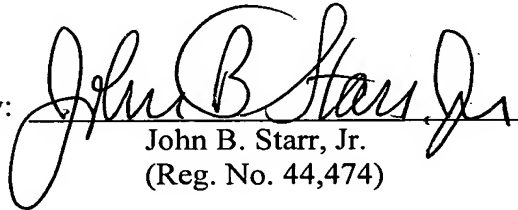
Applicants hereby petition under 37 C.F.R. § 1.136 for an extension of time to reply of THREE MONTHS for which a fee of \$1,020.00 is due under 37 C.F.R. § 1.17(a).

**AUTHORIZATION TO DEBIT DEPOSIT ACCOUNT**

The Commissioner is hereby authorized to debit deposit account 11-0600 in the amount of \$ 1,020.00 for the extension fee due herewith under 37 C.F.R. § 1.17(a). Applicants respectfully submit that no additional fee is due with this paper. If an additional fee is due, the Commissioner is hereby authorized to debit deposit account 11-0600 in the amount of such fee.

Dated: April 13, 2006

By:



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